

Good afternoon,

I am Dr. Howard Mann, Chairman of the Human Subjects and Research Committee, an IRB within Intermountain Health Care, Salt Lake City. The IRB operates under a Multiple project Assurance and serves four community-based hospitals, and outpatient and walk-in clinics, in which clinical trials are conducted.

I would like to comment on items encompassed within questions 3 and 4. I shall leave a printed copy of my comments which includes the references I mention.

"If information about financial interests is disclosed to potential participants in clinical trials, what information should be disclosed and at what level of detail?"

First, an IRB should include sections in the Application for Research that are comprised of specific questions relating to the source, mechanism and amount of funding associated with the trial; the contractual hierarchy associated with the trial (for example : Sponsor, Contract Research Organization, institution, investigator, as applicable); and information concerning any ownership or other beneficial interests the investigators, or the institution with which the investigators are affiliated, have in such sponsoring organizations.

I shall reference and leave a copy of my IRB's Application for Research, containing the questions we ask<sup>1</sup>.

Our guiding principle in this regard is well enunciated by Article 7.3 in the Canadian Tri-Council's Statement: Ethical Conduct for Research Involving Humans<sup>2</sup>, which states, in part: "Budgets for clinical trials usually are calculated by per capita costs, that is, the sponsor pays the researcher a fixed sum for each research subject recruited. Per capita payments raise ethical concerns because of the potential to place the researcher in a conflict between maximizing economic remuneration and serving the best health interests of subject-patients, especially if the researcher also holds a therapeutic or clinical or other fiduciary relationship with the subjects."

This principle of disclosure should also apply to applications for other kinds of research; for example, research involving human biological material. It is increasingly common for academic researchers -- and their affiliated institutions -- to have direct ownership, or other beneficial interests in, for-profit biotechnology companies, in which the research is actually conducted, in whole or in part.

---

<sup>1</sup><http://www.ihc.com/ldsh/irb/forms/application.wpd>

<sup>2</sup><http://www.nserc.ca/programs/ethics/english/sec07.htm>

"Should disclosure (sic) information and institutional policy be provided in the informed consent document or in an entirely separate document?"

In formulating our policy, my Committee adopted the approach explicated in an article by Dr. John La Puma entitled *How Much Do You Get Paid If I Volunteer? Suggested Institutional Policy on Reward, Consent and Research*<sup>3</sup>.

Our template<sup>4</sup> for formulation of the Consent Document contains a section entitled *Who is sponsoring this study?* in which the source, mechanism and amount of funding must be disclosed.

Suggested language includes the following : "This study is sponsored by XYZ, Inc., which produces the study drug. It has contracted with ABC, a Contract Research Organization, to conduct and monitor the study. ABC has contracted with the hospital and the study's clinical investigators to perform the study."

"ABC pays the hospital \$xxx for each subject enrolled. The money is kept in a research fund and is used for the direct costs of conducting research, such as maintaining a research office and providing salary support for study coordinators and monitors. The investigator does not receive direct payment."

Or, "ABC pays the investigator \$xxx for each subject he enrolls in the study. The investigator's own direct cost is \$xxx for each subject enrolled, and he plans to use the funds for...."

I thank you for affording me the opportunity to comment on these questions and share my Committee's approach with you.

---

<sup>3</sup>La Puma, J. *How Much Do You Get Paid If I Volunteer? Suggested Institutional Policy on Reward, Consent and Research Hosp & Health Serv Admin* 39:2, 1994

<sup>4</sup>[http://www.ihc.com/ldsh/irb/consent\\_template.html#SPONSOR](http://www.ihc.com/ldsh/irb/consent_template.html#SPONSOR)

**HUMAN SUBJECTS AND RESEARCH COMMITTEE, URBAN CENTRAL REGION**

IRB# \_\_\_\_\_

**APPLICATION FOR CLINICAL RESEARCH**

( revision dated : 07/22/2000)

**PART A**

1. **PRINCIPAL INVESTIGATOR:**

(For each co-investigator, describe briefly : 1) the investigator's role in the study and 2) the investigator's affiliation and credentials with respect to his participation.. For studies involving FDA-regulated articles, the listed investigators must correspond with that submitted on Form 1572.)

2. **CO-INVESTIGATORS:**

I.

3. **A. TITLE OF STUDY:** \_\_\_\_\_ **PHASE ( if applicable) :** I II III IV (Circle One)

4. **B. Has this study previously been submitted to, and reviewed by, another IRB or IRBs ?** Yes\_\_\_\_ No\_\_\_\_

If *yes*, and the study was *not* approved by an IRB, please provide details and the names of the IRBs concerned:

5. **SUMMARY DESCRIPTION OF STUDY ( Background and Purpose ) :**

6. **IF THE STUDY INVOLVES INVESTIGATION OF A MEDICAL DEVICE, COMPLETE ONE OF THE FOLLOWING:**

Is the Device a Significant Risk Device? ( <http://www.fda.gov/oc/oha/IRB/toc8.html>) Yes\_\_\_\_ No\_\_\_\_

If *yes*, provide the IDE number accorded this investigation by the FDA :

If *no*, substantiate this claim below:

7. **DURATION OF STUDY:**

8. **MULTICENTER STUDY:** Yes\_\_\_\_ No\_\_\_\_

9. **NUMBER OF SUBJECTS TO BE ENROLLED:**

i. Describe the general process involved in recruiting subjects and the enrollment procedures:

ii. If you answer yes to any one of the following, please provide additional details :

- a. Are you going to recruit your own patients for this study ?      Yes \_\_\_\_\_ No \_\_\_\_\_
- b. Are you going to identify potential subjects from hospital or clinic records, logbooks, OR schedules or any other institutional database ?      Yes \_\_\_\_\_ No \_\_\_\_\_
- c. Are you going to identify potential subjects from an extramural data/tissue repository or disease database ?  
Yes \_\_\_\_\_ No \_\_\_\_\_
- d. Are you going to use commercial advertisements ( including the Internet) to recruit subjects ?      Yes \_\_\_\_\_ No \_\_\_\_\_
- e. Are you, the Sponsor or Contract Research Organization going to offer " finder's fees" for the referral of potential subjects ?  
Yes \_\_\_\_\_ No \_\_\_\_\_
- f. Does the study's Sponsor or Contract Research Organization offer financial incentives or bonuses to anyone involved in the study for recruitment of subjects ?      Yes \_\_\_\_\_ No \_\_\_\_\_
- g. Are you going to use the services of a commercial company to identify and recruit potential subjects ?      Yes \_\_\_\_\_ No \_\_\_\_\_

10. HEALTH STATUS OF SUBJECTS:

Does subject group include healthy volunteers?

Yes \_\_\_\_\_ No \_\_\_\_\_

Does subject group include critically ill patients?

Yes \_\_\_\_\_ No \_\_\_\_\_

11. VULNERABLE SUBJECTS :

a. Are prisoners being recruited for the study ?

Yes \_\_\_\_\_ No \_\_\_\_\_

b. Will the study involve subjects with impaired, or potentially impaired, decisional capacity with respect to the provision of Informed Consent ?      Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please describe in detail...

(<http://bioethics.gov/capacity/Informed.htm#Procedures>)

i. The means you are going to use to assess the subject's capacity to provide Informed Consent for participation :

II. How you are going to obtain consent for participation if the potential subject is determined not to have decisional capacity:

12. AGES OF SUBJECTS:

Are any subjects under 18 years -of -age?      Yes \_\_\_\_\_ No \_\_\_\_\_

Are any subjects under 12 years-of-age?      Yes \_\_\_\_\_ No \_\_\_\_\_

13. ASSENT FROM MINORS

Do you plan to use an "assent" form for youths ( ages 13-18 ) ?      Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please attach it to the application.

14. SUMMARY OF RESEARCH-RELATED RISKS TO SUBJECTS :

15. SUMMARY OF POTENTIAL BENEFITS TO SUBJECTS, IF ANY (include financial compensation, if any):

16. RESEARCH USING HUMAN BIOLOGICAL MATERIALS

Tissue banking and genetic research require an expanded concept of informed consent. Does the proposed research involve any of the following:

Long term storage of human biological material?

Yes\_\_\_ No\_\_\_

Transformation of tissue samples into immortalized cell lines?

Yes\_\_\_ No\_\_\_

Long term storage of genetic material and/or genetic research ?

Yes\_\_\_ No\_\_\_

If yes, please complete and submit the *Application For Research Involving Human Biological Materials* available from the *Download Forms* page of the IRB's website ( <http://www.ihc.com/ldsh/irb>). A separate Consent Document must be submitted – formulate this document according to our template ( <http://www.ihc.com/ldsh/irb/hbmttemplate.html> )

17. ADDITIONAL COSTS ASSOCIATED WITH RESEARCH PROJECT:

a. Describe those expenses (additional hospital length of stay; lab/radiology tests; extra clinic visits, etc.) not associated with usual clinical care, but necessary for the conduct of this research study.

b. Describe the nature and operation of the research fund, if any, established to cover these costs.

18. DESCRIPTION OF CONSENT PROCESS:

a. List the names of the individuals who will interview the subject for the purpose of obtaining informed consent, and their relationship to the study :

b. Provide details concerning the training and qualifications of these individuals with respect to their role in this process:

c. When will this interview be conducted relative to the anticipated time of initiation of the study protocol ?

( Note : The IRB recommends that the interview concerning enrollment occur at least several days before the anticipated initiation of the study unless *clinical* considerations preclude this )

19. MONITORING OF DATA AND SUBJECT SAFETY

a. Will this study have a Data and Safety Monitoring Board ( DSMB ) or similar safety committee ?

Yes \_\_\_\_\_ No \_\_\_\_\_

b. If yes, has the sponsor made explicit arrangements for prompt transmission of a pertinent summary of the DSMB's report to you?

Yes \_\_\_\_\_ No \_\_\_\_\_

20. STUDY LOCATION(S):

21. SPONSOR AND/OR GRANTING AGENCY:

Which of the following entities is sponsoring this research ( circle one ) :

- A. A federal granting agency.
- B. A non-profit granting entity.
- C. A commercial company.

Provide additional details, including the name/s of the entities concerned:

If the sponsor is a commercial company ( pharmaceutical, biotechnology or Contract Research Organization ) , complete the following :

i. With whom ( or which entity ) has the company contracted to conduct the research ?

ii. Provide general details concerning the sponsorship provided by the company :

Block grant amount : \$ \_\_\_\_\_ , to \_\_\_\_\_

Capitated payment : a. \$ \_\_\_\_\_ to \_\_\_\_\_ (institution or department), per subject enrolled.

b. \$ \_\_\_\_\_ to principal investigator, per subject enrolled.

22. FINANCIAL CONFLICT OF INTEREST :

The IRB believes it is important to avoid, minimize or mitigate financial conflicts of interest that investigators may have with respect to a proposed research project. This may necessitate appropriate disclosure to the subject in the Consent Document. ( [http://www.ihc.com/ldsh/irb/consent\\_template.html#SPONSOR](http://www.ihc.com/ldsh/irb/consent_template.html#SPONSOR) ) If the proposed research involves investigation of a drug, device or any other biologic material, please complete the following sections :

Do you or your co-investigators receive financial support or reimbursement of any kind, directly or indirectly, from the sponsor or producer of the study article, or from any intermediary with which the sponsor has contracted, such as a Contract Research Organization ?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, complete the following :

- i. Is payment made directly to you or a co-investigator/s ?      Yes \_\_\_\_\_ No \_\_\_\_\_
- ii. Is payment made to a entity in which you, your spouse or dependent children have an ownership or other beneficial interest ?  
( Examples : a Contract Research Organization ( CRO) or similar entity ; a Professional Services Corporation)

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes to i. or ii., please provide additional details including disclosure of the payment amount per enrolled subject :

iii. Do you, or any of your co-investigators, have any one of the following with respect to the Sponsor or , if applicable, the Contract Research Organization :

An equity or membership interest ( including stock options ) in the company ?

Yes \_\_\_\_\_ No \_\_\_\_\_

An interest as a paid consultant ?

Yes \_\_\_\_\_ No \_\_\_\_\_

An interest as a member of the company's management team or board ?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, provide additional details :

iv. If you are employed by, or affiliated with, a health-care institution, and it has a relationship with the sponsor that involves any one of the foregoing, or has executed a technology transfer or royalty agreement with the sponsor, please provide additional details :

**CHECKLIST:** Before submitting this application, ascertain that you have also completed and attached the following:

1. A Consent Document, which must be formulated according to our template: [http://www.ihc.com/ldsh/irb/consent\\_template.html](http://www.ihc.com/ldsh/irb/consent_template.html)
2. A Protocol Summary ( Part B of this form)
3. A copy of the Case Report Form for studies involving FDA-regulated articles.

23. PRINCIPAL INVESTIGATOR'S SIGNATURE:

DATE:

ADDRESS\*\*:

PHONE:

\*\*LIST ADDRESS WHERE CORRESPONDENCE SHOULD BE SENT

E-MAIL ADDRESS :

---

PRIMARY REVIEWER'S COMMENTS AND RECOMMENDATIONS :

Signature of Reviewer

Date

COMMITTEE ACTION:

Approved \_\_\_\_ Approved with Changes \_\_\_\_ Disapproved \_\_\_\_ Tabled \_\_\_\_

CHAIRPERSON'S SIGNATURE :

DATE :

FOLLOW-UP ACTIONS AND DECISIONS:

**Instructions:** Please start this section on a new page. This summary should not be more than three pages . Describe the study in a manner comprehensible to those outside of your speciality. Use a word processor, expanding each section as necessary.

1. Title
2. Background  
( This section should be used to provide a rationale for the conduct of the study. Refer to existent or preliminary studies as necessary)
3. Specific Objectives  
( Enumerate the objectives and nature of the measured end-points. Justify the use of surrogate clinical end-points as necessary)
4. Study design  
( Explicate the nature of the study – observational vs experimental. Differentiate between cohort, case-control, cross-sectional and randomized clinical trials. For the latter, provide sufficient supporting justification for the experimental arm. If it is a placebo-controlled trial, justify this with specific reference to this article: <http://www.sshrc.ca/english/programinfo/policies/Sec07.htm#D>)
5. Subject Selection  
( Include an enumeration of inclusion and exclusion criteria)
6. Statistical methods, data analysis and interpretation  
( Include the factors considered in determining an appropriate sample size)
7. Study Procedures  
(Describe the chronological flow of the study, using schematic diagrams as necessary. Distinguish clearly between treatment-related [medically-indicated] and research-related procedures the subject will undergo)

---

FOR COMMITTEE USE ONLY

These are approved amendments to the study pertinent to this summary:

- 1.